OPTN Member Evaluation Plan Introduction

OPTN members agree to comply with OPTN obligations, which are set forth in the National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq*., the OPTN Final Rule, 42 CFR Part 121, OPTN bylaws, and OPTN policies. The OPTN Member Evaluation Plan is provided as guidance for members on how UNOS, as the OPTN contractor, conducts its ***routine*** reviews and evaluations of members for compliance with the OPTN obligations.

Members are expected to comply with all obligations, regardless of whether it is an obligation specifically described in the OPTN Member Evaluation Plan as one that is "routinely" monitored. Reports of non-compliance with any of the obligations will be investigated by UNOS.

Routine review and evaluation activities performed by UNOS include:

1. Reviewing applications submitted for OPTN membership and designation as an organ-specific transplant program and/or living donor recovery hospital
2. Reviewing applications for mandatory key personnel for maintenance of organ specific transplant program and/or living donor recovery hospital designation.
3. Monitoring member actions associated with program inactivation or re-activation, and requests for withdrawal from the OPTN.
4. Monitoring member program and OPO performance-related data including graft and patient survival rates, organ procurement rates and transplant rates.
5. On-site surveys of individual member compliance with OPTN obligations
6. Reviewing all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN requirements, and investigating potential policy violations, including when:
    - An organ is accepted for one candidate, but another candidate is transplanted
    - Candidates on a match run are skipped or bypassed in order to allocate the organ to a candidate further down the match run
    - An organ is transplanted into an individual who did not appear on the match run
    - An organ is exported to a foreign country prior to exhausting the match run
    - A 0-ABDR kidney is not offered to the appropriate number of 0-ABDR candidates prior to allocating to non-0-ABDR candidates
    - Allocation of double kidneys from a donor who did not meet double kidney criteria
7. Investigating issues reported to UNOS or discovered during routine reviews of OPTN members, including:
    - Potential patient safety events
    - Potential donor-derived disease transmission events
    - Living donor adverse events
    - Vessels recovered from a living donor or a donor positive for hepatitis B/hepatitis C that were transplanted into someone other than the recipient of that donor's organ
    - Complaints
    - Reports or allegations of potential member noncompliance with OPTN obligations

For more information on OPTN member requirements and obligations, see:

1. National Organ Transplant Act, as amended, 42 U.S.C. 273 *et seq*.
2. OPTN Final Rule, 42 CFR Part 121
3. Article I: Membership of the OPTN bylaws
4. Appendix D of the OPTN bylaws
5. Appendix L of the OPTN bylaws

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Policy 2.2: OPO Responsibilities

Effective Date: 2/1/2014

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- An authorization to donate
- Reasons for excluding any donors from the eligible death definition
- Declaration of death note, including
  - Date and time of pronouncement of death
  - Signature(s) of the person(s) required under the relevant state's laws
- Serum archival noted in the donor chart

Review a sample of deceased donor records to verify that data reported through UNet℠ is consistent with source documentation, including:

- HLA typing
- Infectious disease test results

OPOs will provide:

The requested sample of deceased donor medical records

Policy 2.3: Evaluating and Screening Potential Deceased Donors

Effective Date: 2/1/2014

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- That the OPO reviewed the donor's medical record
- That the OPO completed a physical exam including vital signs
- That the OPO attempted to obtain the donor's medical and behavioral history

OPOs will provide:

The requested sample of deceased donor medical records

Policy 2.4: Deceased Donor Medical and Behavioral History

Effective Date: 9/1/2014

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- Any evidence in the medical social history that the donor was exposed to or received HPDGH
  - If the donor was exposed to or received HPDGH, that this was communicated to the receiving transplant programs
- The donor was screened for increased risk for disease transmission
- Whether or not the donor was defined by the OPO as increased risk
- If defined as increased risk, that this information was communicated to all receiving transplant programs

OPOs will provide:

The requested sample of deceased donor medical records

Policy 2.5: Hemodilution Assessment

Effective Date: 9/1/2015

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- The calculations used to determine hemodilution
- Any transfusions of blood products or other intravenous fluids provided to the donor
- The date and time of the blood draw for the blood used for the serological screening tests
- The date and time of the blood draw used to determine hemodilution
- If the donor samples are hemodiluted:
  - That the donor was designated as increased risk in UNet℠
  - That the following were communicated to the accepting transplant programs:
    - Any screening results from the hemodiluted specimens.
    - The tests completed on the hemodiluted specimens
    - The hemodilution calculation used for the hemodiluted specimens, if requested

OPOs will provide:

The requested sample of deceased donor medical records

Policy 2.6.A: Deceased Donor Blood Type Determination

Effective Date: 2/1/2014

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- The results of two blood typing tests
- If the two tests were completed on blood drawn at the same date and time, then documentation showing that the tests were run by two different laboratories

OPOs will provide:

The requested sample of deceased donor medical records

Policy 2.6.B: Deceased Donor Blood Subtype Determination

Effective Date: 5/1/2015

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- When the donor's blood type was reported in UNet℠ as blood type A, non-A1, that there are two results from two pre-transfusion typings that show the donor as blood type A, non-A1.
- When the donor's blood type was reported in UNet℠ as blood type AB, non-A1B, that there are two results from two pre-transfusion typings that show the donor as blood type AB, non-A1B.
- If the two tests were completed on blood drawn at the same date and time, then documentation showing that the tests were run by two different laboratories.
- If there are discordant subtyping results, subtype is not reported.

OPOs will provide:

The requested sample of deceased donor medical records

Additional Guidance:

A hospital's electronic medical record (EMR) can be a source document for lab results when the performing lab's results are directly uploaded into the EMR.

Policy 2.6.D: Secondary Reporting of Deceased Donor Blood Type and Subtype

Effective Date: 2/1/2014

At OPOs, site surveyors will:

Review the OPO's internal policies, procedures and/or protocols to verify that they include a description of the process for:

- Verification that the individual performing the secondary reporting consulted source documents from two blood type tests
- If sub-type of non-A1 or non-A1B is reported:
  - Verification that two individuals separately reported the donor's blood type to the OPTN Contractor
  - Verification that both individuals consulted source documents from two blood type tests

OPOs will provide:

The OPO's internal policies, procedures and protocols for the management of deceased donors

Policy 2.7: HIV Screening of Potential Deceased Donors

Effective Date: 9/1/2014

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- That results of HIV tests were negative

OPOs will provide:

The requested sample of deceased donor medical records

Policy 2.8: Required Deceased Donor General Risk Assessment

Effective Date: 9/1/2014

At OPOs, site surveyors will:

Review a sample of deceased donor records for documentation that there are results or other evidence that the following were performed:

- Arterial blood gas (ABG)
- Chest x-ray
- Urinalysis within 24 hours before cross clamp

OPOs will provide:

The requested sample of deceased donor medical records

Policy 2.9: Required Deceased Donor Infectious Disease Testing

Effective Date: 8/10/2015

At OPOs, site surveyors will:

Review a sample of deceased donor records for documentation that there are results or other evidence that the following were performed:

- Blood and urine cultures
- Infectious disease testing for *all* deceased donors:
  - HIV testing using either:
    - HIV antibody (anti-HIV) donor screening test
    - HIV antigen/antibody (Ag/Ab) combination test
  - Hepatitis B surface antigen (HBsAg) screening test
  - Hepatitis B core antibody (anti-HBc) screening test
  - Hepatitis C antibody screening test (anti-HCV)
  - Hepatitis C ribonucleic acid (RNA) screening or diagnostic nucleic acid test (NAT)
  - Cytomegalovirus (CMV) antibody (anti-CMV) screening or diagnostic test
  - Epstein-Barr Virus (EBV) antibody (anti-EBV) screening or diagnostic test
  - Syphilis screening or diagnostic test
- Additional infectious disease testing for any deceased donor identified as increased risk according to the U.S. PHS Guideline criteria (except donors whose only increased risk factor is receiving hemodialysis within the preceding 12 months) using *either*:
  - HIV RNA by NAT
  - HIV Ag/Ab combination test

Review deceased donor records when an OPO performs diagnostic testing for Hepatitis B, Hepatitis C, or HIV (with the exception of the HIV antigen/antibody combination test) to verify that the OPO:

- Documented in the donor record which test was used
- Provided this information to the receiving transplant hospitals before transplant
- Reported the reason for using a different test to the OPTN Improving Patient Safety portal within 24 hours of organ recovery

OPOs will provide:

The requested sample of deceased donor medical records

Evidence as needed to verify compliance

Additional Resources:

FDA-approved screening and diagnostic tests http://tinyurl.com/FDA-SCREENING

Policy 2.11.B: Required Information for Deceased Liver Donors

Effective Date: 9/1/2014

At OPOs, site surveyors will:

Review a sample of deceased liver donor records for documentation of:

- Results or other evidence that direct bilirubin was performed
- Results or other evidence that total bilirubin was performed

OPOs will provide:

The requested sample of deceased donor medical records

Policy 2.11.C: Required Information for Deceased Heart Donors

Effective Date: 9/1/2014

At OPOs, site surveyors will:

Review a sample of deceased heart donor records for documentation that:

- There are results or other evidence that a cardiology consult or echocardiogram was performed

OPOs will provide:

The requested sample of deceased donor medical records

Policy 2.11.D: Required Information for Deceased Lung Donors

Effective Date: 9/1/2014

At OPOs, site surveyors will:

Review a sample of deceased lung donor records for documentation of:

- A sputum gram stain

OPOs will provide:

The requested sample of deceased donor medical records

Policy 2.11.E: Required Information for Deceased Pancreas Donors

Effective Date: 9/1/2014

At OPOs, site surveyors will:

Review a sample of deceased pancreas donor records for documentation of:

- Serum amylase

OPOs will provide:

The requested sample of deceased donor medical records

Policy 2.13: Post Recovery Follow Up and Reporting

Effective Date: 9/1/2014

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- Evidence of timely follow-up on deceased donor test results post-recovery
- Evidence that any post-recovery positive test results are reported to each recipient hospital via phone call or email within 24 hours of the OPO's receipt of the test results
- The name of the individual who received the report of any post-recovery positive test results
- The mode or method of the report of results (by either telephone or email)
- The date and time the OPO received the results

OPOs will provide:

The requested sample of deceased donor medical records

Policy 2.13.A: Reporting Requirements

Effective Date: 9/1/2014

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- Any infectious diseases or malignancies that may adversely affect a potential transplant recipient, and are identified as such in the chart, are reported to each recipient hospital
- Any previously undocumented diseases or malignancies on biopsy reports or autopsies that may be transmitted to transplant recipients are reported through the patient safety portal

OPOs will provide:

The requested sample of deceased donor medical records

Policy 2.14: Deceased Donor Management

Effective Date: 9/1/2015

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- Fluid intake and output were monitored by the OPO

OPOs will provide:

The requested sample of deceased donor medical records

Policy 2.15.B: Organ Procurement Procedures

Effective Date: 9/1/2014

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- All flush solutions and additives
- All flush solution and additive lot numbers

OPOs will provide:

The requested sample of deceased donor medical records

Policy 3.2: Notifying Patients of Their Options

Effective Date: 2/1/2014

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- The transplant recipient was notified that he or she could register at more than one transplant hospital
- This information
  - Must be provided prior to registration

Transplant hospitals will provide:

The requested sample of medical records

Policy 3.3.A: Blood Type Determination before Registration on the Waiting List

Effective Date: 2/1/2014

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation, including:

- Two blood type tests
  - With different blood draw times
  - With results timed prior to the patient's registration on the waiting list

Transplant hospitals will provide:

The requested sample of medical records

Additional Guidance:

Members are required to retain documentation that two source documents were referenced by each person entering blood type. Data entry in UNet℠ is not sufficient documentation of this element.

A hospital's electronic medical record (EMR) can be a source document for lab results when the performing lab's results are directly uploaded into the EMR.

Policy 3.5: Patient Notification

Effective Date: 2/1/2014

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- Notification of listing letters meet the following requirements:
  - Letter sent within 10 business days of listing
  - Accurate date of listing in the letter
  - Reference to the OPTN Contractor's Patient Information Letter
- Notification of removal letters meet the following requirements:
  - Letter sent within 10 business days of removal from the waiting list
  - Reference to the OPTN Contractor's Patient Information Letter

Transplant hospitals will provide:

The requested sample of medical records

Additional Resources:

Patient Information Letter: http://optn.transplant.hrsa.gov/resources/informing-patients

Policy 3.6.C: Individual Waiting Time Transfers

Effective Date: 9/1/2015

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- The transplant hospital notified the candidate within 10 days after receiving notification from the OPTN Contractor that the candidate's waiting time has been transferred to the hospital

Transplant hospitals will provide:

The requested sample of medical records

Policy 3.9: Removing Candidates from the Waiting List

Effective Date: 9/1/2015

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation, including:

- If the candidate was transplanted, that the date of first anastomosis was no more than one day before the transplant recipient was removed from the waiting list
- If the candidate was removed for death, that the date of knowledge of death was no more than one day before the transplant recipient was removed from the waiting list

Transplant hospitals will provide:

The requested sample of medical records

Policy 5.6: Blood Type Verification upon Receipt

Effective Date: 2/1/2014

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- The following were verified between organ arrival and implantation:
  - Donor blood type
  - Recipient blood type
  - Donor ID
- The following are documented:
  - Organ arrival time or documentation showing organ present at time of verification
  - Verification time
  - Anastomosis time or documentation showing verification occurred prior to implant

Transplant hospitals will provide:

The requested sample of medical records

Additional Guidance:

For purposes of this policy, a living donor organ is not considered "received" until it has been recovered.

If a member is splitting an enbloc kidney and will be transplanting it into two separate candidates, they need to document two separate blood type verifications - one prior to the transplant of each recipient. If an enbloc kidney is whole and being placed into one candidate, then the member needs to document a single episode of verification upon receipt and prior to implantation for the one candidate.

Policy 6.1.A: Adult Heart Status 1A Requirements

Effective Date: 2/1/2014

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation, including:

- All information reported on the adult Status 1A justification form including any of the following listing criteria that are reported:
  - Assistance with mechanical circulatory support
  - Assistance with mechanical circulatory support with device-related complications
  - Assistance with continuous mechanical ventilation
  - Continuous hemodynamic monitoring and daily dosages of the following meet minimums for:
    - Dobutamine
    - Dopamine
    - Milrinone
    - Epinephrine
    - Norepinephrine
  - Exception

Transplant hospitals will provide:

The requested sample of medical records

Policy 6.1.D: Pediatric Heart Status 1A Requirements

Effective Date: 2/1/2014

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation, including:

- All information reported on the pediatric Status 1A justification form, including any of the following listing criteria that are reported:
  - Assistance of a mechanical ventilator
  - Assistance of a mechanical assist device
  - Assistance of a balloon pump
  - Less than six months old at the time of listing under this criteria, and:
    - Diagnosis of congenital or acquired heart disease
    - Pulmonary hypertension at >50%
  - Daily dosages of the following meet minimums for:
    - Dobutamine
    - Dopamine
    - Milrinone
    - Epinephrine
    - Norepinephrine
  - Life expectancy of less than 14 days

Transplant hospitals will provide:

The requested sample of medical records

Policy 6.2: Status Updates

Effective Date: 2/1/2014

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation, including:

- That a candidate's listing status or criteria used to justify the current listing status are updated in UNet℠ within 24 hours of a change in the candidate's medical condition to accurately reflect the change in condition

Transplant hospitals will provide:

The requested sample of medical records

Policy 8.4.A: Waiting Time for Candidates Registered at Age 18 Years or Older

Effective Date: 12/4/2014

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation, including:

- Creatinine clearance less than or equal to 20 mL/min
- GFR less than or equal to 20 mL/min
- Start date of regularly administered dialysis for End Stage Renal Disease (ESRD)

Transplant hospitals will provide:

The requested sample of medical records

Additional Guidance:

A hospital may use discretion in defining the start date of regularly administered dialysis for ESRD as long as there is documentation (i.e., 2728 form, physician's note, dialysis center documentation) of the date entered.

The dialysis start date from the CMS database, if displayed in UNet℠, may be used as documentation supporting the start date of regularly administered dialysis for ESRD entered by the hospital. The hospital is not required to print out the information from UNet℠.

Policy 8.4.B: Waiting Time for Candidates Registered prior to Age 18

Effective Date: 12/4/2014

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation, including:

- Start date of regularly administered dialysis for End Stage Renal Disease (ESRD)

Transplant hospitals will provide:

The requested sample of medical records

Additional Guidance:

A hospital may use discretion in defining the start date of regularly administered dialysis for ESRD as long as there is documentation (i.e., 2728 form, physician's note, dialysis center documentation) of the date entered.

The dialysis start date from the CMS database, if displayed in UNet℠, may be used as documentation supporting the start date of regularly administered dialysis for ESRD entered by the hospital. The hospital is not required to print out the information from UNet℠.

Policy 8.5.A: Candidate Classifications

Effective Date: 12/4/2014

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ for candidates with an Expected Post-Transplant Survival (EPTS) in the top 20% is consistent with source documentation, including:

- Date of birth
- Start date of regularly administered dialysis for End Stage Renal Disease (ESRD)
- Diabetes status
- Number of prior solid organ transplants

Transplant hospitals will provide:

The requested sample of medical records

Additional Guidance:

The dialysis start date from the CMS database, if displayed in UNet℠, may be used as documentation supporting the start date of regularly administered dialysis for ESRD entered by the hospital. The hospital is not required to print out the information from UNet℠.

A hospital may use discretion in defining the start date of regularly administered dialysis for ESRD as long as there is documentation (i.e., 2728 form, physician's note, dialysis center documentation) of the date entered.

Policy 8.5.C: Informed Consent for Kidneys Based on KDPI Greater than 85%

Effective Date: 12/4/2014

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- Candidates reported in UNet℠ as willing to receive offers for kidneys with a Kidney Donor Profile Index (KDPI) score greater than 85% gave written informed consent to receive offers for kidneys with a KDPI score greater than 85%

Transplant hospitals will provide:

The requested sample of medical records

Additional Guidance:

Additional consent is not required to receive offers of kidneys with a KDPI greater than 85% for candidates who were registered on the kidney waiting list before December 4, 2014, and were consented to receive ECD kidney offers.

Policy 8.5.E: Allocation of Kidneys by Blood Type

Effective Date: 5/1/2015

At transplant hospitals, site surveyors will:

Review a sample of medical records, any material incorporated into the medical record by reference, and the transplant program's written policy regarding its titer threshold for transplanting blood type A, non-A1 and blood type AB, non-A1B kidneys into candidates with blood type B to verify that:

- When the program confirmed a candidate's eligibility in UNet℠, the candidate's most recent titer results met the threshold established in the transplant program's internal policy

Transplant hospitals will provide:

The requested sample of medical records

The transplant hospital's internal policies, procedures and protocols for the care of candidates and recipients

Policy 8.5.G: Highly Sensitized Candidates

Effective Date: 12/4/2014

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- For candidates receiving priority based on a Calculated Panel Reactive Antibody (CPRA) score of 99% or 100%:
  - The transplant program's HLA laboratory director and the candidate's transplant physician or surgeon has signed a written approval of the candidate's unacceptable antigens
  - The written approval was provided before the UNet℠ entry of the approvers' names

Transplant hospitals will provide:

The requested sample of medical records

Additional Guidance:

The written approval in the candidate's medical record must occur on the same date or on an earlier date than the approval is documented in UNet℠.

Written approval may be in the form of a physical or electronic signature. The hospital's internal policies regarding requirements for electronic signatures apply. Entry in UNet℠ does not qualify as an electronic signature.

Policy 9.1.A: Adult Status 1A Requirements

Effective Date: 9/1/2015

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation, including:

Qualifying criteria reported on the status 1A justification form for:

- Fulminant liver failure
- Primary non-function
- Hepatic Arterial Thrombosis
- Acute decompensated Wilson's disease
- Special case - information included in the Status 1A application narrative

Transplant hospitals will provide:

The requested sample of medical records

Policy 9.1.B: Pediatric Status 1A Requirements

Effective Date: 9/1/2015

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation, including:

Qualifying criteria for:

- Fulminant liver failure
- Primary non-function
- Hepatic Arterial Thrombosis
- Acute decompensated Wilson's disease
- Special case - information included in the Status 1A application narrative

Transplant hospitals will provide:

The requested sample of medical records

Policy 9.1.C: Pediatric Status 1B Requirements

Effective Date: 9/1/2015

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation, including any of the following information if it is submitted on a liver candidate's application for status 1B:

Qualifying criteria for:

- Non-metastatic hepatoblastoma
- Urea cycle defect or organic acidemia
- Chronic liver disease

Transplant hospitals will provide:

The requested sample of medical records

Policy 9.2: Status and Laboratory Values Update Schedule

Effective Date: 2/1/2014

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation, including:

- The following lab results that affect the MELD score:
  - Creatinine
  - Bilirubin
  - INR
  - 24 hours of CVVHD or dialysis twice in the week prior to modification date (if applicable)

- The following lab results that affect the PELD score:
  - Albumin
  - Bilirubin
  - INR
  - Growth failure variables (height, weight, gender)
  - 24 hours of CVVHD or dialysis twice in the week prior to modification date (if applicable)

- That all lab results listed above were the most recent available at the time they were entered into UNet℠

Transplant hospitals will provide:

The requested sample of medical records

Policy 9.3.C: Specific MELD/PELD Exceptions

Effective Date: 9/1/2015

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation, including:

- Diagnosis and narrative content reported on the MELD or PELD exception application

Transplant hospitals will provide:

The requested sample of medical records

Policy 9.3.F: Candidates with Hepatocellular Carcinoma (HCC)

Effective Date: 10/8/2015

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation, including:

- The following information on the initial exception application:
  - Lesion numbers and sizes
  - Lesion characteristics (if applicable)
    - Increased contrast enhancement on late hepatic arterial image
    - Washout on portal venous/delayed phase
    - Peripheral rim enhancement on delayed phase
    - Growth by 50% or more documented on serial MRI or CT obtained < 6 months apart
  - Alpha-fetoprotein level
  - Assessment/ablative therapies (if applicable)
  - Extrahepatic spread documentation
  - Original/presenting tumor evaluation
  - Narrative information (if applicable)

- The following information on subsequent exception extension applications:
  - Lesion numbers and sizes
  - Alpha-fetoprotein level
  - Previously reported loco-regional treatments (if applicable)
  - Newer loco-regional treatments (if applicable)
  - Tumor resections since the initial application (if applicable)
  - Narrative information (if applicable)

Transplant hospitals will provide:

The requested sample of medical records

Policy 9.3.G: MELD/PELD Score Exception Extensions

Effective Date: 9/1/2015

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation, including:

- Diagnosis and narrative content reported on the MELD or PELD exception application

Transplant hospitals will provide:

The requested sample of medical records

Policy 10.1.F: The LAS Calculation

Effective Date: 2/19/2015

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation, including:

- All variables that can affect the LAS
  - Date of birth
  - Height
  - Weight
  - Diagnosis
  - Functional status
  - Diabetes status
  - Assisted ventilation status
  - Oxygen status
  - Oxygen rate
  - Forced vital capacity (FVC)
  - 6 minute walk distance
  - Pulmonary artery systolic pressure
  - Cardiac index (CI)
  - Central venous pressure (CVP)
  - PCO2
  - PCO2 type
  - Serum creatinine
  - Total bilirubin

Transplant hospitals will provide:

The requested sample of medical records

Policy 10.1.G: Reporting Additional Data for Candidates with an LAS of 50 or Higher

Effective Date: 2/1/2015

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation, including:

- Variables reported within 14 days of a candidate's LAS becoming 50 or higher:
  - Assisted ventilation status
  - Oxygen rate
  - Oxygen status
  - Current PCO2
  - PCO2 type

Review a sample of medical records, and any material incorporated into the medical record by reference, for results or other evidence that the following were performed:

- Assessment and reporting of these variables every 14 days while a candidate's LAS remains 50 or higher

Transplant hospitals will provide:

The requested sample of medical records

Additional Guidance:

A transplant program is only required to report an updated PCO2 type and value if the test was performed within the previous 14 days.

Policy 10.2.B: Lung Candidates with Exceptional Cases

Effective Date: 7/1/2014

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation, including:

- Data reported on the LRB exception application

Transplant hospitals will provide:

The requested sample of medical records

Policy 11.3.B: Kidney-Pancreas Waiting Time Criteria for Candidates At Least 18 Years Old

Effective Date: 9/1/2015

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that data reported through UNet℠ is consistent with source documentation, including:

- Kidney criteria
  - Creatinine clearance less than or equal to 20 mL/min
  - GFR less than or equal to 20 mL/min
  - Start date of regularly administered dialysis for End Stage Renal Disease (ESRD)
- Pancreas criteria
  - On insulin
  - C-peptide value
  - Height used for BMI calculation (if C-peptide value is greater than 2)
  - Weight used for BMI calcuation (if C-peptide value is greater than 2)

Transplant hospitals will provide:

The requested sample of medical records

Additional Guidance:

A hospital may use discretion in defining the start date of regularly administered dialysis for ESRD as long as there is documentation (i.e., 2728 form, physician's note, dialysis center documentation) of the date entered.

The dialysis start date from the CMS database, if displayed in UNet℠, may be used as documentation supporting the start date of regularly administered dialysis for ESRD entered by the hospital. The hospital is not required to print out the information from UNet℠.

Policy 13.2: Potential KPD Donor Requirements for Participation

Effective Date: 2/1/2014

At Living Donor recovery hospitals, site surveyors will:

Review a sample of KPD donor medical records, and any material incorporated into the medical record by reference, to verify that data reported through UNet℠ is consistent with source documentation, including:

- The donor's date of birth

Recovery hospitals will provide:

The requested sample of living donor records

Policy 13.11: Transportation of Kidneys

Effective Date: 2/1/2014

At Living Donor recovery hospitals, site surveyors will:

Review a sample of KPD donor medical records, and any material incorporated into the medical record by reference, for documentation of a plan detailing:

- The location where the recovered kidney will be picked up for transport to the recipient hospital
- The name and telephone number of every person or company who will package and label the kidney
- The date and time that the plan was documented
    - This must be before the potential donor entered the operating room for the kidney recovery surgery

Recovery hospitals will provide:

The requested sample of living donor records

Policy 14.1.A: Living Donor Psychosocial Evaluation Requirements

Effective Date: 2/1/2015

At Living Donor recovery hospitals, site surveyors will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the donor psychosocial evaluation was completed and addressed the following:

- Psychosocial issues that might complicate the living donor's recovery
- Risks for poor psychosocial outcome
- Behaviors that may increase risk for disease transmission as defined by the U.S. PHS Guideline
- The living donor's history of smoking, alcohol, and drug use, abuse, and dependency
- Factors that warrant educational or therapeutic intervention prior to the final donation decision
- The living donor's understanding of the short and long-term medical and psychosocial risks for both the living donor and recipient
- Whether the decision to donate is free of inducement, coercion, and other undue pressure
- The living donor's ability to make an informed decision
- The living donor's ability to cope with the major surgery and related stress
- Whether the donor has a realistic plan for donation and recovery, with social, emotional and financial support available as recommended
- The living donor's occupation, employment status, health insurance status, living arrangements, and social support
- The living donor's understanding of the potential financial implications of living donation

Interview relevant staff, and substantiate the information obtained in the interview through review of internal policies, procedures and/or protocols; a sample of living donor medical records; or any material incorporated into the medical record by reference to obtain evidence that the hospital's standard practice is:

- That the person performing psychosocial evaluations of living donors is someone with the role/title of psychiatrist, psychologist, masters-prepared social worker, or licensed clinical social worker

Recovery hospitals will provide:

The requested sample of living donor records

The recovery hospital's internal policies, procedures and protocols for the care of living donors

Evidence as needed to verify compliance

Access to relevant staff who can answer interview questions

Policy 14.2.A: ILDA Requirements for Living Donor Recovery Hospitals

Effective Date: 2/1/2015

At Living Donor recovery hospitals, site surveyors will:

Interview relevant staff, and substantiate the information obtained in the interview through review of internal policies, procedures and/or protocols; a sample of living donor medical records; or any material incorporated into the medical record by reference to obtain evidence that the hospital's standard practice is:

- To designate a key ILDA contact for each living kidney or living liver donor
- That the ILDA is not involved with the recipient evaluation
- That the ILDA is independent of the decision to transplant the recipient
- That the ILDA discusses with each donor, the:
  - Informed consent process
  - Evaluation process
  - Surgical procedure
  - Medical and psychosocial risks
  - Follow-up requirements and the benefit and need for participating in follow-up

Recovery hospitals will provide:

The requested sample of living donor records

The recovery hospital's internal policies, procedures and protocols for the care of living donors

Access to relevant staff who can answer interview questions

Additional Guidance:

Site surveyors will examine the hospital's internal policies, procedures and/or protocols to verify the presence of a process by which the hospital ensures that the assigned ILDA for a given potential living donor patient is not involved in the evaluation of the associated transplant candidate, and is not involved in the decision to proceed to transplantation or approve the transplant candidate for transplantation.

Policy 14.2.B: ILDA Protocols for Living Donor Recovery Hospitals

Effective Date: 2/1/2015

At Living Donor recovery hospitals, site surveyors will:

Review the living donor recovery hospital's internal policies, procedures and/or protocols to verify that the hospital has developed and implemented written protocols that address:

- Composition of the ILDA team, if a team is used
- Qualifications and training of the ILDA
- Duties and responsibilities of the ILDA
- Grievance process for the ILDA

Recovery hospitals will provide:

The recovery hospital's internal policies, procedures and protocols for the care of living donors

Policy 14.3: Informed Consent Requirements

Effective Date: 9/1/2015

At Living Donor recovery hospitals, site surveyors will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for a document signed by the living donor confirming that the donor:

- Is willing to donate
- Is free from inducement or coercion
- Has been informed that he/she may decline to donate at any time

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that:

- The donor was offered an opportunity to discontinue the donor consent or evaluation process in a way that is protected and confidential
- An ILDA was available to assist the donor during the consent process

Interview relevant staff, and substantiate the information obtained in the interview through review of internal policies, procedures and/or protocols; a sample of living donor medical records; or any material incorporated into the medical record by reference to obtain evidence that the hospital's standard practice is:

- To provide information to donors in a language in which the donor is able to engage in a meaningful dialogue with the recovery program staff

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided information or disclosure to the donor stating that:

- The recovery hospital will take all reasonable precautions to provide confidentiality for both:
  - The donor
  - The recipient
- It is a federal crime for any person to knowingly acquire, obtain, or otherwise transfer any human organ for anything of value
- That the hospital must (or will) provide an ILDA
- A deceased donor kidney might become available for the recipient before the donor evaluation is completed or the living donor transplant occurs
- Any transplant candidate might have risk factors for increased morbidity or mortality that are not disclosed to the donor
- The health information obtained during the evaluation will be subject to the same regulations as all medical records
- The medical evaluation could reveal conditions that must be reported to local, state or federal public health authorities
- The recovery hospital is required to report living donor follow-up information at six months, one year, and two years post-donation
- Any infectious disease or malignancy pertinent to acute recipient care discovered during the first two years of the donor's post-operative follow-up care:
  - May need to be reported to local, state or federal public health authorities
  - Will be disclosed to their recipient’s transplant center
  - Will be reported through the OPTN Improving Patient Safety Portal
- The donor will receive a medical evaluation
- The donor will receive a psychosocial evaluation
- The hospital may refuse the donor
- The following are inherent risks associated with evaluation for living donation:
  - Allergic reactions to contrast
  - Discovery of reportable infections
  - Discovery of serious medical conditions
  - Discovery of adverse genetic findings
  - Discovery of abnormalities that may require additional testing at the donor's expense or create the need for unexpected decisions by the transplant team

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided information or disclosure to the donor addressing the risk of the following:

- Death
- Scars, hernia, wound infection, blood clots, pneumonia, nerve injury, pain, fatigue, and other consequences typical of any surgical procedure
- Abdominal symptoms such as bloating, nausea, and bowel obstruction
- The morbidity and mortality of the donor may be impacted by obesity, hypertension, or other donor-specific pre-existing conditions
- Problems with body image
- Post-surgery depression or anxiety
- Feelings of emotional distress or grief if the transplant recipient experiences any recurrent disease or if the recipient dies
- Changes to the donor's lifestyle from donation
- Personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed
- Need for life-long follow-up at the donor's expense
- Loss of employment or income
- Negative impact on the ability to obtain future employment
- Negative impact on the ability to obtain, maintain, or afford health, disability, and life insurance
- Future health problems experienced by living donors following donation may not be covered by the recipient's insurance
- Risks may be temporary or permanent
- Risks may include those listed, but are not limited to those listed

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided the following information to the donor regarding outcome and survival data:

- When the recipient transplant hospital is known (or is the same as the recovery hospital):
  - SRTR's national 1-year patient and transplanted organ survival rates for the organ being transplanted
  - SRTR's most recent hospital-specific 1-year patient and transplanted organ survival rates for the recipient's transplant hospital for the organ being transplanted

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided additional information or disclosure specific to the living kidney donor regarding:

- Education about expected post-donation kidney function and the potential impact on chronic kidney disease (CKD) and end-stage renal disease (ESRD) on the living kidney donor in the future, including:
  - On average, donors may have a 25-35% permanent loss of kidney function after donation
  - Baseline risk of ESRD for living kidney donors does not exceed that of members of the general population with the same demographic profile
  - Living donor risks must be interpreted in light of the known epidemiology of both CKD and ESRD. When CKD or ESRD occurs, CKD generally develops in mid-life (40-50 years old) and ESRD generally develops after age 60
  - The medical evaluation of a young donor cannot predict lifetime risk of CKD or ESRD
  - Living donors may be at a higher risk for CKD if they sustain damage to the remaining kidney
  - The development of CKD and subsequent progression to ESRD may be more rapid with only one kidney
  - Dialysis is required if the donor develops ESRD
  - Current practice is to prioritize prior living kidney donors who become kidney transplant candidates according to OPTN policy
- Potential medical or surgical risks
  - Decreased kidney function
  - Kidney failure and the need for dialysis or kidney transplant for the donor
  - Risks may be temporary or permanent
  - Risks may include those listed, but are not limited to those listed

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the recovery hospital provided additional information or disclosure specific to the living liver donor regarding:

- Potential medical or surgical risks
  - Acute liver failure with need for liver transplant
  - Transient liver dysfunction with recovery
  - Risk of red cell transfusions or other blood product transfusions
  - Biliary complications, including leak or stricture, that may require additional intervention
  - Post-donation laboratory tests may result in abnormal or false positive results that may trigger additional tests that have associated risks
- Living liver donor recipient outcome and survival data when the recipient transplant hospital is known (or is the same as the recovery hospital):
  - SRTR's most recent hospital-specific 1-year living donor recipient survival and living donor graft survival rates for the recipient's transplant hospital

<u>Recovery hospitals will provide:</u>

The requested sample of living donor records

The recovery hospital's internal policies, procedures and protocols for the care of living donors

Evidence as needed to verify compliance

Access to relevant staff who can answer interview questions

Policy 14.4.A: Living Donor Blood Type Determination

Effective Date: 2/1/2014

At Living Donor recovery hospitals, site surveyors will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that there are results for:

- Two separately completed blood type tests, and
  - That the two separately completed blood type tests are based on two separate blood samples drawn at different times prior to recovery

Recovery hospitals will provide:

The requested sample of living donor records
Evidence as needed to verify compliance

Policy 14.4.A.i: Living Donor Blood Subtype Determination

Effective Date: 5/1/2015

At Living Donor recovery hospitals, site surveyors will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that there are results for:

- Two separately completed subtyping tests, and
  - That the two separately completed subtyping tests were based on two separate blood samples drawn at different times

Recovery hospitals will provide:

The requested sample of living donor records
Evidence as needed to verify compliance

Policy 14.4.B: Living Donor Medical Evaluation Requirements

Effective Date: 8/10/2015

At Living Donor recovery hospitals, site surveyors will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that the donor medical evaluation was completed.

Interview relevant staff, and substantiate the information obtained in the interview through review of internal policies, procedures and/or protocols; a sample of living donor medical records; or any material incorporated into the medical record by reference to obtain evidence that the hospital's standard practice is:

- That the medical evaluation of the living donor performed at the recovery hospital is reviewed by a physician or surgeon

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that an evaluation of the donor included assessment of:

- Personal history of:
  - Hypertension
  - Diabetes
  - Lung disease
  - Heart disease
  - Gastrointestinal disease
  - Autoimmune disease
  - Neurologic disease
  - Genitourinary disease
  - Hematologic disorders
  - Bleeding or clotting disorders
  - Cancer, including melanoma
- History of infections
- The donor's active and past medications
- The donor's allergies
- Coronary artery disease
- Whether the donor has a family history of:
  - Coronary artery disease
  - Cancer
- Occupation
- Employment status
- Health insurance status
- Living arrangements
- Social support
- Smoking, alcohol and drug use/abuse
- Psychiatric illness
- Depression
- Suicide attempts
- Increased risk behavior as defined by the U.S. PHS Guideline

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that there are results for:

- Height
- Weight
- BMI
- Vital signs
- A review of major organ systems
- Complete Blood Count (CBC) with platelet count
- Blood type (and subtype if tested)
- Prothrombin Time (PT) or International Normalized Ratio (INR)
- Partial Thromboplastin Time (PTT)
- Metabolic testing, including:
  - Electrolytes
  - BUN
  - Creatinine
  - Albumin
  - Calcium
  - Phosphorus
- HCG quantitative pregnancy test (for premenopausal women without surgical sterilization)
- Chest X-ray
- Electrocardiogram (ECG)
- CMV (Cytomegalovirus) antibody testing
- EBV (Epstein Barr Virus) antibody testing
- Syphilis testing
- Infectious disease testing performed no earlier than 28 days before organ recovery:
  - HIV antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination test
  - Hepatitis B surface antigen (HBsAg) testing
  - Hepatitis B core antibody (anti-HBc) testing
  - Hepatitis C antibody (anti-HCV) testing
  - Hepatitis C ribonucleic acid (RNA) by nucleic acid test (NAT)
- Additional infectious disease testing for any living donor identified as increased risk according to the U.S. PHS Guideline criteria (except donors whose only increased risk factor is receiving hemodialysis within the preceding 12 months) using either:
  - HIV RNA by NAT
  - HIV Ag/Ab combination test

Review the living donor recovery hospital's internal policies, procedures and/or protocols to verify that the hospital has developed and implemented written protocols that address:

- Identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease
- Cancer screening for:
  - Cervical cancer
  - Breast cancer
  - Prostate cancer
  - Colon cancer
  - Lung cancer

Recovery hospitals will provide:

The requested sample of living donor records
The recovery hospital's internal policies, procedures and protocols for the care of living donors
Evidence as needed to verify compliance
Access to relevant staff who can answer interview questions

Policy 14.4.C: Additional Requirements for the Medical Evaluation of Living Kidney Donors

Effective Date: 2/1/2015

At Living Donor recovery hospitals, site surveyors will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that an evaluation of the donor included assessment of:

- A kidney-specific personal history including:
  - Genetic renal diseases
  - Kidney disease
  - Proteinuria
  - Hematuria
  - Kidney injury
  - Diabetes, including gestational diabetes
  - Nephrolithiasis
  - Recurrent urinary tract infections
- Whether the donor has a family history of:
  - Kidney disease
  - Diabetes
  - Hypertension
  - Kidney cancer
- The donor's anatomy, including:
  - Whether kidneys are of equal size
  - Whether kidneys have masses, cysts, stones or other anatomical defects
  - Which kidney is more suitable for transplantation

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that there are results for:

- Blood pressure
  - Taken on two occasions, or 24-hour monitoring, or overnight monitoring
- Metabolic testing, including:
  - Fasting blood glucose
  - Fasting lipid profile, including:
    - Cholesterol
    - Triglycerides
    - HDL Cholesterol
    - LDL Cholesterol
  - Glucose tolerance test or glycosylated hemoglobin, if indicated (in first degree relatives of diabetics and in high risk individuals)
- Urinalysis or urine microscopy
- Measurement of urinary protein and albumin excretion
- Measurement of glomerular filtration rate (GFR) by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection
- 24-Hour urine stone panel (if indicated according to policy)

Review the living donor recovery hospital’s internal policies, procedures and/or protocols to verify that the hospital has developed and implemented written protocols that address:

- PKD screening

Recovery hospitals will provide:

The requested sample of living donor records
The recovery hospital's internal policies, procedures and protocols for the care of living donors
Evidence as needed to verify compliance

Policy 14.4.D: Additional Requirements for the Medical Evaluation of Living Liver Donors

Effective Date: 2/1/2015

At Living Donor recovery hospitals, site surveyors will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that an evaluation of the donor included assessment of:

- Whether the donor has a family history of:
  - Liver diseases
  - Bleeding or clotting disorders
- The donor's anatomy via radiological assessment, including:
  - Assessment of projected graft volume
  - Donor's remnant volume
  - Vascular anatomy
  - Presence of steatosis

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that there are results for:

- Hepatic function panel
- Ceruloplasmin, if indicated (in donors with a family history of Wilson's disease)
- Iron, iron binding capacity and ferritin
- Alpha-1-antitrypsin level
  - Phenotype for living donors with low alpha-1-antitrypsin levels

Review the living donor recovery hospital's internal policies, procedures and/or protocols to verify that the hospital has developed and implemented written protocols that address:

- Hypercoagulable state evaluation
- Testing for genetic diseases
- Screening for autoimmune disease
- Pre-donation liver biopsy

Recovery hospitals will provide:

The requested sample of living donor records

The recovery hospital's internal policies, procedures and protocols for the care of living donors

Evidence as needed to verify compliance

Policy 14.5: Registration and Blood Type Verification of Living Donors before Donation

Effective Date: 2/1/2015

At Living Donor recovery hospitals, site surveyors will:

Review the living donor recovery hospital's internal policies, procedures and/or protocols to verify that the hospital has developed and implemented written protocols that address:

- Verification by someone other than the person who entered the ABO on the living donor feedback form that:
  - ABO was entered correctly
  - ABO was entered using the ABO source documents from an initial and second determination

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, to verify that data reported through UNet℠ is consistent with source documentation, including:

- That the ABO information entered for the donor at registration is correct, by comparing the results in UNet℠ with the blood type source documents from an initial and second determination
- Verifying that the dates and times shown on the source documents are prior to the date and time of the blood type data entry into UNet℠ for donor registration

Recovery hospitals will provide:

The requested sample of living donor records

The recovery hospital's internal policies, procedures and protocols for the care of living donors

Evidence as needed to verify compliance

Additional Guidance:

Source documentation for blood type results must be lab results.

A hospital's electronic medical record (EMR) can be a source document for lab results when the performing lab's results are directly uploaded into the EMR.

Policy 15.1: Patient Safety Contact

Effective Date: 9/1/2015

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- Reporting of post-recovery cultures relevant to potential transmission of disease or medical conditions to all recipient transplant programs

OPOs will provide:

The requested sample of deceased donor medical records

Policy 15.3: Informed Consent of Transmissible Disease Risk

Effective Date: 2/1/2015

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- The potential recipient gave consent when the organ offered met PHS increased risk criteria

Transplant hospitals will provide:

The requested sample of medical records

Policy 15.4.A: Transplant Program Requirements

Effective Date: 2/1/2014

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- Reporting through the patient safety portal of all malignancies or infectious diseases discovered after recovery

OPOs will provide:

The requested sample of deceased donor medical records

Policy 15.4.B: Requirements for Living Donor Recovery Hospital and Host OPOs

Effective Date: 9/1/2015

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- Reporting of any post-recovery cultures relevant to potential transmission of disease or medical conditions to all recipient transplant programs

OPOs will provide:

The requested sample of deceased donor medical records

Policy 16.1: Organs Not Requiring Transport

Effective Date: 2/1/2014

At Living Donor recovery hospitals, site surveyors will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that:

- "Time outs" were performed
  - Before leaving the donor operating room
  - After arrival in the potential recipient's operating room
  - According to the hospital's internal policies, procedures, and/or protocols

Review the living donor recovery hospital's internal policies, procedures and/or protocols to verify that the hospital has developed and implemented written protocols that address:

- "Time outs"
  - That they include a process for verifying:
    - A unique identifier for the donor
    - A unique identifier for the recipient
  - That they are performed two times:
    - In the donor operating room
    - In the potential recipient's operating room, before anastomosis

Recovery hospitals will provide:

The requested sample of living donor records
The recovery hospital's internal policies, procedures and protocols for the care of living donors

Policy 16.6: Verification of Information before Shipping

Effective Date: 2/1/2014

At OPOs, site surveyors will:

Review a sample of deceased donor records for the following documentation:

- Someone at the OPO, other than the individual who initially performed the labeling and documentation, has verified the accuracy of each label

OPOs will provide:

The requested sample of deceased donor medical records

Policy 16.7.A: Vessel Recovery and Transplant Use

Effective Date: 2/1/2014

At transplant hospitals, site surveyors will:

Interview staff members that have been designated to oversee the storage and use of vessels, to verify knowledge that:

- vessels should only be used in implantation or modifications of organ transplants
- any vessels shared with another transplant hospital must be reported to the OPTN
- vessel disposition (including use and disposal) must be reported to the OPTN

Transplant hospitals will provide:

Access to relevant staff who can answer interview questions

Additional Guidance:

The receiving transplant hospital is not required to report vessels as shared when it receives vessels directly from the recovering OPO.

All vessels shared between hospitals must be reported, even if they are not used.

Policy 16.7.B: Vessel Storage

Effective Date: 10/22/2015

At transplant hospitals, site surveyors will:

Review the transplant hospital's internal policies, procedures and/or protocols and/or interview key clinical personnel to verify that they address:

- That vessels from donors who are HCV antibody positive, HCV nucleic acid test (NAT) positive, HBV surface antigen (HBsAg) positive, or HBV NAT positive are not stored for later use
- Having vessel information available to the transplant surgeon at all times
- Storage, monitoring, and disposing of vessels
- Monitoring the temperature of the refrigerator where the vessels are stored
- Destruction of vessels within 14 days after the recovery date
- Notifying the OPTN of vessel disposition within 7 days after use, sharing, or discard
- That a person has been designated to oversee the storage, monitoring, and disposal of vessels

Review temperature monitoring logs for the review period to verify that:

- The temperature of the vessel storage refrigerator was maintained no lower than 2° C or higher than 8° C during the audit time frame
- There were daily security and temperature checks

Visually inspect currently stored vessels to verify that:

- The vessels are packaged and labeled as required by Policy 16.4: Packaging and Labeling

Review compliance rates for:

- Destruction of vessels within 14 days after recovery
- Reporting vessel disposition within 7 days after use, sharing, or discard

Transplant hospitals will provide:

The transplant hospital's internal policies, procedures and protocols for the care of candidates and recipients

Evidence as needed to verify compliance

Access to relevant staff who can answer interview questions

Policy 18.1: Data Submission Requirements

Effective Date: 9/1/2015

At OPOs, site surveyors will:

Review rates of compliance with submission dates for the following forms submitted to the OPTN within the review timeframe:

- Deceased Donor Registration (DDR)
- Deceased Donor Feedback
- Potential Transplant Recipient (PTR) refusal codes

OPOs will provide:

At Living Donor recovery hospitals, site surveyors will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that:

- The date and time of the registration of the donor via UNet℠ occurred before the date and time of the start of the recovery

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, to verify that data reported through UNet℠ is consistent with source documentation, including:

- The following donor information is reported on the LDR:
  - Donor ID
  - Donor date of birth
  - SSN
  - ABO
  - Serologies
  - Height
  - Weight
  - Conversion from laparoscopic
  - Organ recovery date
  - Organ recovered
  - Recipient name
  - Recipient SSN
  - Recovery facility
  - Workup facility
  - Discharge date

Review rates of compliance with submission dates for LDRs submitted to the OPTN within the review timeframe.

Recovery hospitals will provide:

The requested sample of living donor records
Evidence as needed to verify compliance

Additional Guidance:

When calculating the due date for deceased donor feedback forms, the procurement date is defined as the date the donor entered the operating room for purposes of organ recovery.

Policy 18.5.A: Reporting Requirements after Living Kidney Donation

Effective Date: 3/31/2015

At Living Donor recovery hospitals, site surveyors will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, to verify that data reported through UNet℠ is consistent with source documentation, including:

- Presence of supporting documentation in the donor chart for answers to each of the following:
  - Most recent donor status since [date of last follow-up form submission]
  - Working for income
  - Loss of insurance due to donation
- Presence of supporting documentation in the donor chart when any of the following are answered on the LDF:
  - Cause of death
  - If [not working for income], not working due to
  - If [loss of insurance due to donation], loss of:
    - Health insurance
    - Life insurance
- Presence of supporting documentation in the donor chart when any of the following are answered "yes" on the living kidney donor LDF:
  - Donor readmitted since last LDR or LDF form was submitted?
  - Kidney complications
  - Maintenance dialysis
  - Donor developed hypertension requiring medication
  - Diabetes
- The lab values entered on the living kidney donor LDF for
  - Serum creatinine
  - Urine protein or protein-creatinine ratio

Recovery hospitals will provide:

The requested sample of living donor records

Evidence as needed to verify compliance

Policy 18.5.B: Reporting Requirements after Living Liver Donation

Effective Date: 3/31/2015

At Living Donor recovery hospitals, site surveyors will:

Review a sample of living donor medical records, and any material incorporated into the medical record by reference, to verify that data reported through UNet℠ is consistent with source documentation, including:

- Presence of supporting documentation in the donor chart for answers to each of the following:
  - Most recent donor status since [date of last follow-up form submission]
  - Working for income
  - Loss of insurance due to donation
- Presence of supporting documentation in the donor chart when any of the following are answered on the LDF:
  - Cause of death
  - If [not working for income], not working due to
  - If [loss of insurance due to donation], loss of:
    - Health insurance
    - Life insurance
- Presence of supporting documentation in the donor chart when any of the following are answered "yes" on the living liver donor LDF:
  - Donor readmitted since last LDR or LDF form was submitted?
  - Liver complications, including
    - Abscess
    - Bile leak
    - Hepatic resection
    - Incisional hernia due to donation surgery
    - Liver failure
    - Registration on the liver candidate waiting list
- The lab values entered on the living liver donor LDF for
  - Alanine aminotransferase
  - Alkaline phosphatase
  - Platelet count
  - Total bilirubin

Recovery hospitals will provide:

The requested sample of living donor records
Evidence as needed to verify compliance

Bylaws Appendix B.1: OPO Compliance

Effective Date: 9/1/2012

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- The OPTN contractor learns of a final adverse action taken by a regulatory agency against an OPO which was not reported to the OPTN contractor in writing as defined in the bylaws

OPOs must:

Notify the OPTN contractor when any regulatory agency takes action against the OPO. Notification must:

- Be in writing
- Be received by the OPTN contractor within 10 business days after the OPO receives notification of the final adverse action
- Include all documents relating to the final adverse action to the OPTN contractor

Definitions:

Final adverse actions by an agency:
Include, but are not limited to any of the following:

- Decertification by the Center for Medicare and Medicaid Services (CMS)
- Any action by a state licensing authority that affects the organization's ability to function
- Any action by the state health department that affects the organization's ability to function
- Loss of accreditation by the Association of Organ Procurement Organizations (AOPO), American Association of Tissue Banks (AATB), or Joint Commission on Accreditation of Healthcare Organizations

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896
- By E-mail: to your regional Performance Review contact (http://transplantpro.org/wp-content/uploads/Regional_Map_Staff.pdf)

Bylaws Appendix B.2: OPO Performance Requirements

Effective Date: 9/1/2012

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- An OPO meets or falls below all of the following thresholds for a single organ or all organs taken together:
  - Expected organ yield per 100 donors - observed organ yield per 100 donors > 10
  - Ratio of observed to expected yield < .90
  - Two-sided p-value less than 0.05
- An OPO is noncompliant with MPSC requests or fails to adopt and implement a plan for improvement

The MPSC will review blinded data derived from UNet℠ to:

- Identify whether observed organ yields fall below the expected yield, given individual OPO donor characteristics
- Evaluate overall (or aggregate) organ yield
- Evaluate organ-specific yields

Staff will send inquiries on behalf of the MPSC:

- When an OPO is identified as having experienced lower than expected yields during a specified 2.5 year cohort
- That may include a request for continued reporting until observed organ yields improve
- That may include a requirement for the OPO to promptly adopt and implement a plan for improvement
- That may lead to consideration for adverse action, if the OPO does not comply

MPSC monitoring may include:

- A request for continued reporting until observed organ yields improve
- A requirement for the OPO to promptly adopt and implement a plan for improvement.

OPOs must:

Cooperate with the performance review process if yields meet or fall below thresholds. This may include:

- Responding to inquiries regarding performance
- Complying with MPSC recommendations regarding performance
- Participating in an informal discussion regarding a performance review
- Participating in a peer visit to identify opportunities for improvement
- Formulating a plan for quality improvement

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896
- By E-mail: to your regional Performance Review contact (http://transplantpro.org/wp-content/uploads/Regional_Map_Staff.pdf)

Bylaws Appendix B.3: Quality Assessment and Performance Improvement (QAPI) Requirement

Effective Date: 9/1/2015

How the OPTN contractor will evaluate member compliance with this bylaw:

MPSC monitoring may include:

- Review of an OPO's QAPI program, including documentation that all elements of the program have been implemented

Additional Guidance:

This QAPI requirement will not be routinely monitored by the OPTN Contractor through site survey or other means. The MPSC may request information about an OPO's QAPI program in instances where the MPSC has a serious concern about the OPO's ability to independently improve and maintain compliance with OPTN obligations, such as repeated violations of the same or similar policies or prolonged periods of underperformance.

Bylaws Appendix B.5: OPO Personnel

Effective Date: 9/1/2015

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- A member fails to inform the OPTN contractor of a change in key personnel within 30 days of departure.
- A member fails to submit the replacement's name and curriculum vitae no less than 30 days before the change will take effect.

OPOs must:

Submit written notice immediately (and within 30 days) after learning that the OPO administrative director or medical director plans to leave or otherwise change positions and no longer serve in one of these roles. Written notice of a change in key personnel must include:

- Name of new director
- Status of appointment (interim or permanent)
- Effective date of the change
- A current curriculum vitae

Notify the OPTN contractor if it has not filled a vacant administrative or medical director position permanently within six months. The notification must include the steps taken to fill the position and the timeline for completing the hiring process.

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896
- By E-mail: to Senior Membership Standards Advisor

Bylaws Appendix C.5: Changes in Key Laboratory Personnel

Effective Date: 2/1/2014

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- A member fails to inform the OPTN contractor of a change in key personnel within seven business days of laboratory knowledge of the departure or extended absence
- A member fails to submit a completed personnel change application in the time and manner required
- A member fails to submit an updated laboratory coverage plan in the time and manner required

Histocompatibility Laboratories must:

Notify the OPTN contractor in writing within seven business days of learning that the primary laboratory director, technical supervisor, or clinical consultant plans to leave or end active participation in the laboratory. Written notice of a change in key personnel must include:

- The nature of the change
- The effective date
- If a change in laboratory director, indicate if the technical supervisor and clinical consultant roles also changed
- Confirmation that either ASHI or CAP (consulting subcontractors) have also been notified

Submit an updated laboratory coverage plan at least 30 days before the effective date of the change in key personnel or coverage.

Submit a completed personnel change application any time the laboratory wishes to designate a new laboratory director, technical supervisor, or clinical consultant. The completed application must:

- Demonstrate that the proposed individual meets the requirements for that position
- Be received by the OPTN contractor at least 30 days before the effective date of the change in key personnel

If the laboratory received less than 60 days advance notice of the key personnel's departure or need for temporary leave, the application and coverage plan must be submitted to the OPTN contractor within 30 days of the date of departure.

Definitions:

Changes in laboratory key personnel:
A change in key personnel occurs when an individual in a key personnel role:

- Departs
- Is unavailable to perform responsibilities for more than 30 days (temporary basis)
- Changes position so that he/she no longer serves in a key personnel role
- Accepts additional responsibilities for more than 30 days at another histocompatibility laboratory

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896
- By E-mail: to Senior Membership Standards Advisor

Bylaws Appendix C.6.D: Regulatory Adverse Actions

Effective Date: 2/1/2014

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- The OPTN contractor learns of a final adverse action taken by a regulatory agency against a histocompatibility laboratory, and the histocompatibility laboratory did not report this action to the OPTN contractor as defined in the bylaws

Histocompatibility Laboratories must:

Notify the OPTN contractor when any regulatory agency takes action against the laboratory. Notification must:

- Be in writing
- Be submitted within 10 business days after the histocompatibility laboratory receives notification of the final adverse action
- Provide all documents relating to the final adverse action to the OPTN contractor

Definitions:

Final adverse actions by an agency:
Include, but are not limited to any of the following:

- Decertification by the Center for Medicare and Medicaid Services (CMS)
- Any action by a state licensing authority that affects the organization's ability to function
- Any action by the state health department that affects the organization's ability to function
- Loss of accreditation by the Association of Organ Procurement Organizations (AOPO), American Association of Tissue Banks (AATB), or Joint Commission on Accreditation of Healthcare Organizations

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896
- By E-mail: to Senior Membership Standards Advisor

Bylaws Appendix D.1: Transplant Hospital Compliance

Effective Date: 9/1/2012

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- OPTN contractor learns of a final adverse action taken by a regulatory agency against a transplant hospital, and the transplant hospital did not report this action to the OPTN contractor as defined in the bylaws

Transplant hospitals must:

Notify the OPTN contractor when any regulatory agency takes action against the transplant hospital.
Notification must be:

- In writing
- Received by the OPTN contractor within 10 business days after the transplant hospital receives notification of the final adverse action

The member must provide all documents relating to the final adverse action to the OPTN contractor with the notification

Definitions:

Final adverse actions by an agency:
Include, but are not limited to any of the following:

- Decertification by the Center for Medicare and Medicaid Services (CMS)
- Any action by a state licensing authority that affects the organization's ability to function
- Any action by the state health department that affects the organization's ability to function
- Loss of accreditation by the Association of Organ Procurement Organizations (AOPO), American Association of Tissue Banks (AATB), or Joint Commission on Accreditation of Healthcare Organizations

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896
- By E-mail: to your regional Performance Review contact (http://transplantpro.org/wp-content/uploads/Regional_Map_Staff.pdf)

Bylaws Appendix D.3: Quality Assessment and Performance Improvement (QAPI) Requirement

Effective Date: 9/1/2015

How the OPTN contractor will evaluate member compliance with this bylaw:

MPSC monitoring may include:

- Review of a transplant hospital's QAPI program, including documentation that all elements of the program have been implemented

Additional Guidance:

This QAPI requirement will not be routinely monitored by the OPTN Contractor through site survey or other means. The MPSC may request information about a transplant hospital's QAPI program in instances where the MPSC has a serious concern about the hospital's ability to independently improve and maintain compliance with OPTN obligations, such as repeated violations of the same or similar policies or prolonged periods of underperformance.

Bylaws Appendix D.6: Transplant Program Key Personnel

Effective Date: 9/1/2015

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- The OPTN contractor learns of an active and approved transplant program performing organ transplants without having both a qualified primary surgeon and a qualified primary physician for the organ type in question.

Transplant hospitals must:

Apply for and receive OPTN program designation and approval for any organs being transplanted. A major criterion which must be met requires the submission and approval of applications for a designated primary surgeon and physician who must meet the organ-specific criteria found in the bylaws. All approved transplant programs must:

- Obtain initial primary surgeon and physician approval through initial program application;
- Replace any departing approved primary surgeon or physician with another qualified individual by submitting a key personnel change application; or
- Voluntarily inactivate or withdraw a transplant program with the loss or extended unavailability of its designated primary surgeon or physician until this requirement can be met with a qualified individual.

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896
- By E-mail: to your regional Application Related contact (http://transplantpro.org/wp-content/uploads/Regional_Map_Staff.pdf)

Additional Resources:

Membership Application Forms: http://www.unos.org/donation/index.php?topic=application

Bylaws Appendix D.6.B: Surgeon and Physician Coverage (Program Coverage Plan)

Effective Date: 9/1/2015

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will review materials submitted by members, including coverage plans. Coverage plans will be:

- Reviewed by an ad-hoc committee of the MPSC when submitted with an application
- Reviewed by the MPSC when requested
- Reviewed by an MPSC subcommittee when requested

Transplant hospitals must:

Submit the program's written coverage plan to the OPTN contractor when:

- There is a key personnel change
- Applying for a new transplant program
- Applying for new transplant hospital membership
- Requested by staff

Notify candidates when:

- There are significant program or personnel changes, including:
  - Change in primary transplant physician or surgeon
  - Becoming a single surgeon or single physician program
  - Previously being a single surgeon or single physician program and now are able to again provide 365/24/7 coverage
  - Any other major or substantial programmatic changes that the program feels will impact or alter patients' ability to receive transplant services

Inform patients, if staffed by a single surgeon or physician, that:

- The individual may not be available to the program at all times
- The individual's unavailability may impact patient care, including the program's ability to:
  - Accept organ offers
  - Procure organs
  - Perform transplants

Address each of the following requirements in the program coverage plan

- The program's ability to have at least one transplant surgeon and transplant physician available 365 days a year, 24 hours a day, 7 days a week
- The program provides candidates with a written summary of the program coverage plan
  - When the candidates are listed
  - When there are significant or substantial program or key personnel changes
- That the transplant surgeons and transplant physicians on call for the program cannot be simultaneously on call for another hospital's transplant program that is more than 30 miles away (unless the circumstances have been reviewed and approved by the MPSC)
- That a transplant surgeon or transplant physician is readily available in a timely manner to:
  - Facilitate organ acceptance
  - Facilitate organ procurement
  - Facilitate organ transplantation
  - Address urgent patient issues
- That the primary transplant surgeon and primary transplant physician are not designated as the primary transplant physician or surgeon at another transplant hospital unless both hospitals have additional transplant surgeons and physicians for those programs

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896
- By E-mail: to your regional Application Related contact

(http://transplantpro.org/wp-content/uploads/Regional_Map_Staff.pdf)

Additional Resources:

Membership Application Forms: http://www.unos.org/donation/index.php?topic=application

Bylaws Appendix D.7: Changes in Key Transplant Program Personnel

Effective Date: 9/1/2015

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- A member fails to inform the OPTN contractor of a change in key personnel within seven business days of transplant program knowledge of the departure or extended absence
- A member fails to submit a completed personnel change application in the time and manner required
- A member fails to submit a written notification that the program plans to inactivate or withdraw

Transplant hospitals must:

Notify the OPTN contractor in writing of a change in key personnel within seven business days of transplant program knowledge of the departure or extended absence of the program's primary surgeon or physician (including primary living donor surgeons).

Submit a completed personnel change application any time they wish to designate a new primary physician or surgeon. The completed application must:

- Demonstrate that the proposed surgeon or physician meets the primary surgeon or physician requirements for that organ
- Be received by the OPTN contractor at least 30 days before the effective date of the change in key personnel (due date will be provided by staff)

  If the program received less than 60 days advance notice of a primary physician or surgeon's departure or need for temporary leave, the application must be submitted to the OPTN contractor within 30 days after the program notifies the OPTN contractor of the pending change (due date will be provided by staff)

Voluntarily inactivate or withdraw its designated transplant program status, if:

- The transplant program's primary surgeon or physician ends active involvement with the program on a permanent or temporary basis, and
- The program is unable to:
  - Submit a completed key personnel application by the due date
  - Demonstrate in the application that the proposed replacement meets the primary surgeon or physician requirements

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896
- By E-mail: to your regional Application Related contact (http://transplantpro.org/wp-content/uploads/Regional_Map_Staff.pdf)

Bylaws Appendix D.7.D: Reinstatement of Previously Designated Primary Surgeon or Primary Physician

Effective Date: 9/1/2015

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will review written reinstatement requests.

Transplant hospitals must:

Submit a written reinstatement request if the program wishes to reinstate a previously-designated primary surgeon or primary physician who left the hospital and returned. The request must:

- Be submitted within a year of the individual's departure from the hospital
- Include the following documents:
  - A letter from the transplant program director, department chair, or chief of the division, verifying the individual's current working knowledge and experience.
  - A letter from the individual confirming the individual's on-site availability and commitment to the program.
  - A current letter from the hospital credentialing committee verifying that the individual meets the requirements and is qualified and able to resume as primary surgeon or primary physician.

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896
- By E-mail: to your regional Application Related contact (http://transplantpro.org/wp-content/uploads/Regional_Map_Staff.pdf)

Bylaws Appendix D.10: Review of Transplant Program Functional Activity

Effective Date: 9/1/2015

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- The program has been identified as functionally inactive because it has not performed a transplant during a defined period. The relevant time periods are
  - Kidney, Liver or Heart: 3 consecutive months
  - Pancreas or Lung: 6 consecutive months
  - Stand-alone pediatric programs: 12 consecutive months
- The member does not respond to MPSC inquiries regarding functional inactivity

Transplant hospitals must:

Provide written notice when a transplant program is notified by the MPSC that the program has been identified as functionally inactive to all of the program's

- potential candidates
- candidates registered on the waiting list

The written notice must include:

- The dates identified in the MPSC notification during which no transplants were performed
- The reason no transplants were performed
- The options available to the candidates, including multiple listing or transfer of accrued waiting time to another transplant hospital
- A copy of the OPTN Contractor's Patient Information Letter

Respond to inquiries regarding periods of functional inactivity.

Participate in informal discussion with the MPSC or a subcommittee, if requested.

Additional Guidance:

Programs will not be identified for functional inactivity and referred to the MPSC during the first year after approval or reactivation of the program.

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896
- By E-mail: to your regional Performance Review contact (http://transplantpro.org/wp-content/uploads/Regional_Map_Staff.pdf)

Bylaws Appendix D.11.A: Transplant Program Performance

Effective Date: 9/1/2015

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- The member falls below the established thresholds for review of post-transplant patient or graft survival
- The member does not respond to MPSC inquiries regarding lower than expected outcomes
- The member fails to promptly adopt and implement a plan for quality improvement
- The member fails to inactivate a program or a component of a program or withdraw designated transplant program status when recommended by the MPSC

The MPSC will review blinded data derived from UNet℠ to:

- Identify transplant programs for review that have performed 10 or more transplants within 2.5 years and meet either of the following criteria:
  - A probability greater than 75% that the hazard ratio is greater than 1.2
  - A probability greater than 10% that the hazard ratio is greater than 2.5
- Identify transplant programs for review that have performed nine or fewer transplants within 2.5 years and have:
  - At least one event in a 2.5-year cohort
  - At least one event in subsequent years

Staff will send inquiries on behalf of the MPSC:

- To programs identified as having experienced lower than expected outcomes during a specified 2.5-year cohort

Transplant hospitals must:

- Respond to inquiries and submit all requested documentation
- Participate in an informal discussion when requested by the MPSC
- Promptly adopt and implement a plan for quality improvement
- Participate in an on-site peer visit to identify opportunities for improvement when requested by the MPSC
- Inactivate a program or component of a program or withdraw designated transplant program status when recommended by the MPSC based on patient safety concerns

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896
- By E-mail: to your regional Performance Review contact (http://transplantpro.org/wp-content/uploads/Regional_Map_Staff.pdf)

Bylaws Appendix D.11.B: Patient Notification Requirements for Waiting List Inactivation

Effective Date: 9/1/2015

At transplant hospitals, site surveyors will:

Review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- Transplant programs have provided written notice to candidates each time the program has reached either or both of the inactive waiting list thresholds
- Each element listed in the bylaws was addressed in the notification letter

A copy of the actual letter sent, filed in the medical record, will be sufficient for this documentation provided it contains all required elements.

Transplant hospitals will provide:

The requested sample of medical records

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- The member fails to notify the patients in the time and manner required

Transplant hospitals must:

Respond to inquiries regarding periods of waiting list inactivity

Notify candidates when:

- a program inactivates its waiting list for either:
  - 15 or more consecutive days, or
  - 28 or more cumulative days during a calendar year

The written notice must include:

- The reasons for the inactivity
- The expected length of time the waiting list will be inactive
- The explanation that no organs will be accepted by this program for the candidates during the inactive period
- The candidate's options (must include multiple listing and transferring to another transplant hospital)
- How the candidate will be notified of reactivation or if the period of inactivation is extended
- A copy of the OPTN Contractor's Patient Information Letter
- The dates of each instance of waiting list inactivation (if notice is based on cumulative periods of inactivation)

The notices must also be documented and retained.

Bylaws Appendix F.6.E: Conditional Program Approval Status

Effective Date: 9/1/2012

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will review materials submitted by members:

- The progress of each program toward meeting the requirements for full approval
- A report provided by the transplant program before the end of the first year of conditional approval
- A final report before the end of the approval period, which must document the member's ability to meet the requirements for full approval
- Key personnel change applications proposing a new surgeon that fully meets the primary living donor liver surgeon criteria if the second surgeon does not meet criteria at the end of the conditional approval period

Conditionally approved programs must:

Comply with any interim operating policies and procedures required by the MPSC.

Comply with all applicable policies and procedures.

Demonstrate continuing progress toward full compliance with Criteria for Institutional Membership.

Have both designated surgeons present at all living donor recoveries during the period of conditional approval.

Provide a report one month prior to the conclusion of the first year of conditional approval if the program is still unable to meet all requirements for full approval. The report must document:

- The surgeon's progress toward meeting the bylaw requirement, or
- That the program is making sufficient progress in recruiting a transplant surgeon who meets the criteria for a qualified living donor liver surgeon

Submit the following one month before the conclusion of the second (final) year of conditional approval:

- A report documenting that the surgeon can fully meet the primary living donor liver surgeon requirements, or
- A key personnel change application proposing a replacement surgeon who can fully meet the primary living donor liver surgeon requirements and who will be on-site and credentialed to perform living donor hepatectomies by the end of the conditional approval period

Stop performing living donor liver recoveries by inactivating or relinquishing the living donor component if the program is unable to meet the requirements for full approval at the end of the conditional approval period.

Definitions:

Interim operating procedures:
May be required by the MPSC, and may include:

- Submission of reports describing the surgeon's progress towards meeting the requirements
- Other operating conditions to demonstrate ongoing quality and efficient patient care

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896

- By E-mail: to your regional Application Related contact (http://transplantpro.org/wp-content/uploads/Regional_Map_Staff.pdf)

Bylaws Appendix K.1.A: Program Component Cessation

Effective Date: 9/1/2012

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will review patient notification letters and refer the matter to the MPSC for consideration when:

- The OPTN contractor is notified of transplant program cessation
- Transplant program component cessation notifications do not meet bylaw requirements

Transplant hospitals must:

Notify potential living donors and potential and waitlisted candidates who have expressed interest in living donation when a living donor component of a transplant program is stopped.

Notify potential and waitlisted candidates when a deceased donor component of a transplant program is stopped.

Notify potential and waitlisted pediatric candidates when a pediatric component of a transplant program is stopped.

Notify potential and waitlisted adult candidates and potential and waitlisted pediatric candidates who may turn 18 during the component cessation period when an adult component of a transplant program is stopped.

Maintain documentation supporting patient notification occurred and provide a copy of the patient notification and a list of the patients notified when requested.

The written notice must include:

- The reasons for program component cessation
- Explanation that during this period, the candidate cannot receive an organ offer
- Options for affected patients to transfer to another transplant program
- The phone number to the program's administrative office that can help with transferring to another transplant program

In instances in which a program elects to cease transplant for a subset of patients within a program component, such as infants in a pediatric component, the affected group would be further defined to only include that specific patient population (e.g., infants only).

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896
- By E-mail: to your regional Application Related contact (http://transplantpro.org/wp-content/uploads/Regional_Map_Staff.pdf)

Bylaws Appendix K.3.A: Notice to the OPTN Contractor of Long-term Inactive Status

Effective Date: 9/1/2012

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will review materials submitted by members:

- Written notice to the OPTN contractor of inactivation

Transplant hospitals must:

Send written notification to the OPTN contractor, which must include:

- The reason(s) for inactivation
- The effective date of the inactivation

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896
- By E-mail: to your regional Application Related contact (http://transplantpro.org/wp-content/uploads/Regional_Map_Staff.pdf)

Bylaws Appendix K.3.B: Notice to the Patients of Long-term Inactive Status

Effective Date: 9/1/2015

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- The member fails to submit the required information in the time and manner required
- The member fails to notify the patients in the time and manner required

The OPTN contractor will review materials submitted by members:

- Draft copies of patient notification letters

Transplant hospitals must:

Send to the OPTN Contractor:

- A sample of each type of patient notice
- A list of potential candidates, candidates, recipients, and living donors who received the notice

Send written notification to patients (including potential candidates, candidates, recipients, and living donors currently being treated by the transplant program) at least 30 days prior to the planned inactivation date, or no later than seven days after the effective inactivation date.

The written notice must include:

- The reasons for inactivating the transplant program
- Explanation that although the patient is still on the waiting list, the candidate cannot receive an organ offer through this program while it is inactive
- Options for potential candidates, candidates, recipients, and living donors to transfer to another transplant program
- Prior to being registered as an active candidate at another transplant program, the accepting transplant program will complete an evaluation to determine suitability for registration
- The phone number of the inactive program's administrative office that can help with transferring to another transplant program

Additional Guidance:

If a natural disaster adversely affects the function of a transplant program, the patient notification requirements will be applied reasonably and flexibly.

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896
- By E-mail: to your regional Application Related contact (http://transplantpro.org/wp-content/uploads/Regional_Map_Staff.pdf)

Bylaws Appendix K.4.A: Notice to the OPTN Contractor

Effective Date: 9/1/2012

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will review materials submitted by members:

- Written notice of withdrawal

Transplant hospitals must:

Send written notification to the OPTN contractor, which must include:

- The reason(s) for withdrawal
- The effective date of the withdrawal

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896
- By E-mail: to your regional Application Related contact (http://transplantpro.org/wp-content/uploads/Regional_Map_Staff.pdf)

Bylaws Appendix K.4.B: Notice to the Patients

Effective Date: 9/1/2015

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- The member fails to submit the required information in the time and manner required
- The member fails to notify the patients in the time and manner required

The OPTN contractor will review materials submitted by members:

- Draft copies of patient notification letters

Transplant hospitals must:

Send to the OPTN Contractor:

- A sample of each type of patient notice
- A list of potential candidates, candidates, recipients, and living donors who received the notice

Send written notification to patients (including potential candidates, candidates, recipients, and living donors currently being treated by the transplant program) at least 30 days prior to the planned withdrawal/termination date, or no later than seven days after the effective withdrawal or termination date.

The written notice must include:

- The reasons for withdrawing or terminating the transplant program.
- Explanation that although the patient is still on the waiting list, the candidate cannot receive an organ offer through this program while it is withdrawn.
- Options for potential candidates, candidates, recipients, and living donors to transfer to another transplant program.
- Prior to being registered as an active candidate at another transplant program, the accepting transplant program will complete an evaluation to determine suitability for registration
- The phone number of the withdrawing program's administrative office that can help with transferring to another transplant program.

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896
- By E-mail: to your regional Application Related contact (http://transplantpro.org/wp-content/uploads/Regional_Map_Staff.pdf)

Bylaws Appendix K.5: Transition Plan during Long-term Inactivity, Termination, or Withdrawal

Effective Date: 9/1/2012

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate any allegations of noncompliance

The OPTN contractor will review materials submitted by members:

- Transition plans
- Routine reports

Transplant hospitals must:

Submit a transition plan to the OPTN contractor within seven days of the effective date (may be submitted separately from the initial notice). It must include:

- A list of candidates on the transplant hospital's waiting list, with the following information on each candidate:
  - If the candidate chose to transfer to another hospital, the program to which the candidate is transferring
  - If the candidate chose not to transfer to another hospital:
    - The reason
    - Whether the candidate was informed of the implications of removal from the waiting list
- A list of the most urgent candidates, including:
  - Individualized plans for transfer
  - Potential alternative transplant programs
  - Timeline for transferring those candidates according to priorities and deadlines listed in Bylaw K.5(6)

Submit routine reports to the OPTN contractor until the program has completely cleared its waiting list of both active and inactive candidates. In general, these reports are due on the 1st and 15th of each month.

Immediately stop organ transplantation.

Help potential candidates and candidates transfer to other programs.

Transfer candidates to another hospital when either:

- Requested by the candidate
- The candidate is active and currently hospitalized at the transplant program. Then the transplant program must:
  - Initiate the transfer within 14 days after inactivation, withdrawal or termination, unless any of the following:
    - Transfer would be unsafe
    - Discharge is anticipated within the 14 day time period
    - Circumstances outside the transplant hospital prevent transfer within 14 days
  - Document all efforts to transfer these candidates and submit that documentation to UNOS if a program cannot meet these deadlines

Where to send notification:

- By Mail: UNOS Member Quality
  700 N 4th Street
  Richmond, VA 23219

- By Facsimile: (804) 782-4896
- By E-mail: to your regional Application Related contact (http://transplantpro.org/wp-content/uploads/Regional_Map_Staff.pdf)

Bylaws Appendix K.6: Transferred Candidates Waiting Time

Effective Date: 9/1/2015

How the OPTN contractor will evaluate member compliance with this bylaw:

The OPTN contractor will investigate and refer a member to the MPSC for review when:

- No written progress report is received within 90 days after the actual patient transfer date
- It appears that the member has not complied with their submitted plan
- The OPTN has requested, but not received, an updated progress report

The OPTN contractor will review materials submitted by members:

- The written collective patient transfer agreement and plan submitted by the transplant programs to confirm that it contains all required elements
- Progress reports submitted by the accepting transplant program to confirm that the program is complying with the submitted plan

Transplant hospitals must:

Send to the OPTN Contractor:

- A complete written agreement with each accepting transplant program that will be receiving candidates via a collective transfer that includes:
  - Request for collective transfer of candidates' waiting times
  - List of patient names and identifiers to be transferred
  - Mutually agreed upon transfer date
  - Assurance of notification and patient consent to transfer
  - List of active candidates that the transferring program agrees to change to inactive status if requested by the accepting transplant program
  - Acknowledgement that all patient information and records available to the OPTN Contractor will be transferred without modification
  - Acknowledgement that the transplant program accepting the patients accepts responsibility for patient notification and management according to all applicable OPTN Policies and Bylaws
- A plan from each accepting transplant program for evaluation of all collectively transferred candidates that includes:
  - A timeline and procedure for reviewing each candidate's waiting list status and amending it as appropriate until the candidate has been evaluated in accordance with the program's selection and listing criteria
  - A process and timeline for notifying candidates whose status is changed from active to inactive as part of either the collective transfer agreement or the accepting program's plan
  - An expected timeline for completing the candidates' evaluations and any subsequent waiting list status adjustments needed as a result of the new evaluations
- A progress report from each accepting transplant program:
  - Updating the evaluation status of each collectively transferred candidate as of day 90 post-collective transfer
  - Submitted to the OPTN Contractor within 14 days following day 90 post-collective transfer
- Additional progress reports from each accepting transplant program as requested by the OPTN Contractor

Where to send notification:

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  700 N 4th Street
  Richmond, VA 23219
- By Facsimile: (804) 782-4896
- By E-mail: to your regional Application Related contact (http://transplantpro.org/wp-content/uploads/Regional_Map_Staff.pdf)